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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4071]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Final Guidance for Industry on "Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients" (VICH GL18); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry (#100) entitled "Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients" (VICH GL18). This guidance has been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from a similarly titled guidance regarding pharmaceuticals for human use, which was adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance is intended to recommend acceptable amounts of residual solvents in new animal drugs (referred to as pharmaceuticals or veterinary medicinal products in the final guidance) for the safety of the target animal as well as for the safety of human consumers of products derived from treated food producing animals. It is intended to assist in developing new animal drug applications (referred to as marketing applications in the final guidance) submitted to the European Union, Japan, and the United States.

DATES: You may submit written comments at any time.

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ADDRESSES: You may submit written requests for a single copy of the final guidance entitled "Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients" (VICH GL18) to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

You may submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kevin J. Greenlees (HFV–150), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6977, e-mail, kgreenle@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical requirements for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce the differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the ICH for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the: European Commission; European Medicines Evaluation Agency; European Federation of Animal Health; the U.S. FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; the Japanese Association of Veterinary Biologics; and the Japanese Ministry of Agriculture, Forestry and Fisheries.

Two observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/New Zealand, and one representative from the industry in Australia/New Zealand. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Guidance on Impurities: Residual Solvents

In the **Federal Register** of October 12, 1999 (64 FR 55296), FDA published the notice of availability of the draft guidance entitled "Impurities: Residual Solvents" (VICH GL18) giving interested persons until November 12, 1999, to submit comments. FDA received no comments. The final guidance was submitted to the VICH Steering Committee. At a meeting held on June 14 through 16, 2000, the VICH Steering Committee endorsed the final guidance for industry, VICH GL18.

This guidance is intended to recommend acceptable amounts of residual solvents in new animal drugs (referred to as pharmaceuticals or veterinary medicinal products in the final guidance) for the safety of the target animal as well as for the safety of human consumers of products derived from treated food-producing animals. The guidance is intended to assist in developing new animal drug applications (referred to as marketing applications in the final guidance) submitted to the European Union, Japan, and the United States.

This final level 1 guidance is being issued consistent with FDA's good guidance practices regulation (65 FR 56468, September 19, 2000). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be

be used if such approach satisfies the requirements of applicable statutes and regulations. Information collected is covered under OMB control number 0910–0032.

IV. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cvm.

V. Comments

As with all of FDA's guidances, the public is encouraged to submit written comments with new data or other new information pertinent to this guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may, at any time, submit written or electronic comments regarding this guidance. Written comments should be submitted to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Comments may also be submitted electronically on the Internet at http://www.fda.gov/dockets/ecomments. Once on this Internet site, select "99D–4071 Impurities: Residual Solvents in New Veterinary Medicinal Products" and follow the directions.

Dated: 5-11-01

May 11, 2001.

Margaret M. Dotzel,
Associate Commissioner for Policy.

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